EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David W. Osborne on 09/27/2011.

The Declaration of Niklas Axen under 37 CFR 1.132 filed 06/17/2011 is sufficient to overcome the rejection of the claims based upon the showing of the criticality of the claimed amounts of expanding agent upon curing rate.

Claims 93, 98, 118, and 144 are cancelled.

Claims 73-89, 92, 94-97, 99-117, 119, 120, 130, 140-143, and 145 are allowed.

The Examiner notes that claim numbers 121-129, and 131-139 are missing due to a misnumbering of the claims.

IN THE CLAIMS:

The newly amended claims should read as follows:

73. An injectable pharmaceutical composition comprising:

i) one or more biodegradable hydrating ceramics;

ii) one or more expandable agents, wherein the expandable agent is present in the composition at a concentration of at least about 0.1 % w/w to about 2.5% w/w;

iii) a sorbed aqueous medium wherein the sorbed aqueous medium is present in the composition at a concentration of at the most about 30% w/w to about 60% w/w of the total composition; and iv) one or more therapeutically and/or diagnostically active substances, which is an androgen, an anti-androgen, an oestrogen, an anti-oestrogen, a gestagen, an anti-gestagen, an oligonucleotide, a progestagen, a gonadotropin-releasing hormone, a gonadotropin inhibitor, an adrenal and/or prostate enzyme inhibitor, a membrane efflux and/or membrane transport protein, an immune system modulator, an angiogenesis inhibitor, or combinations thereof, which in solid form has a ruptured structure, and wherein the composition solidifies within 20 minutes or less when stored at 37°C.

92. A pharmaceutical composition according to claim 73; in liquid or semi-solid form.

94. A pharmaceutical composition according to claim 73, wherein the ruptured structure has a shape selected from the group consisting of beads, tubes, polygons, spheres, stars, cubes, or mixtures thereof.

107. A pharmaceutical composition according to claim 73, wherein the
active substance is controllably released from the composition.

116. A composition in particulate form for use in the preparation of an injectable pharmaceutical composition as recited in claim 73, the composition comprising:
i) one or more biodegradable hydrating ceramics in powder form;

ii)one or more expandable agents, in an amount sufficient to be present in the injectable composition at a concentration of at least about 0.1% w/w/ to about 2.5% w/w; and

iii) one or more therapeutically and/or diagnostically active substances, which is an androgen, an anti-androgen, an oestrogen, an anti-oestrogen, a gestagen, an anti-gestagen, an oligonucleotide, a progestagen, a gonadotropin-releasing hormone, a gonadotropin inhibitor, an adrenal and/or prostate enzyme inhibitor, a membrane efflux and/or membrane transport protein, an immune system modulator, an angiogenesis inhibitor, or combinations thereof.

117. A method for the preparation of an injectable pharmaceutical composition as recited in claim 73, comprising;.

a) dispersing a mixture of: i) one or more biodegradable ceramics in powder form, and ii) one or more expandable agents in an amount sufficient to be present in the injectable composition at a concentration of at least about 0.1% w/w to about 2.5% w/w; in an amount of a sorbed aqueous medium sufficient to be present in the injectable composition at a concentration of at the most about 30% w/w to about 60% w/w of the total composition; and

b) adding one or more therapeutically or diagnostically active substances, which is an androgen, an anti-androgen, an oestrogen, an anti-oestrogen, a gestagen, an anti-gestagen, an oligonucleotide, a progestagen, a gonadotropin-releasing hormone, a gonadotropin inhibitor, an adrenal and/or prostate enzyme inhibitor, a membrane efflux and/or membrane transport protein, an immune system modulator, an angiogenesis inhibitor, or combinations thereof, such that in solid for said injectable composition has a ruptured structure, and wherein the injectable composition solidifies within 20 minutes or less when stored at 37°C.

119. A method for treatment of a subject suffering from a prostate disease, comprising administering to the subject an injectable composition as recited in claim 73.

140. A method according to claim 119, wherein the active substance is a combination of anti-androgen and a gonadotropin-releasing hormone.

145. A method according to claim 119, wherein the composition solidifies in vivo after administration.

REASONS FOR ALLOWANCE

The prior art of record does not teach or reasonably suggest an injectable pharmaceutical composition that comprises one or more hydrating ceramics, one or more expandable agents at a concentration of 0.1% w/w to about 2.5% w/w, a sorbed aqueous medium at a concentration of about 30% w/w to about 60% w/w and one or more pharmaceutically or diagnostically active substances, which is an androgen, an anti-androgen, an oestrogen, and anti-oestrogen, a gestagen, an anti-gestagen, a oligonucleotide, a progestagen, a gonadotropin-releasing hormone, a gonadotropin inhibitor, an adrenal and/or prostate enzyme inhibitor, a membrane efflux and/or membrane transport protein, an immune system modulator, an angiogenesis inhibitor, or combinations thereof, which in solid form has a ruptured structure, and wherein the composition solidifies within a time period of about 20 min or less when stored at 37°C.

Applicants have provided a declaration demonstrating a showing of the criticality of the claimed amounts of expanding agent upon curing rate.

Therefore the claims are allowable over the prior art.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-Awadi whose telephone number is (571) 270-7668. The examiner can normally be reached on 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DA/
Examiner, Art Unit 1615

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